APR 1 2 2002

Attachment C – Revised 510(k) Summary

1.0 GENERAL INFORMATION

1.1 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is K020662

1.1.1. Submitter Name, Address, Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(716) 453-4041

Contact Person: Ann M Quinn

1.1.2. Preparation Date

Date 510(k) prepared: February 28, 2002

1.1.3. Device Name

Trade or Proprietary Name:
VITROS Immunodiagnostic Products Troponin I Reagent Pack
VITROS Immunodiagnostic Products Troponin I Calibrators

Common Name : TROPONIN I assay
Classification Name: Troponin I (cTnI) Test System

1.1.4. Predicate Device

The *VITROS* Immunodiagnostic Products Troponin I Reagent Pack and *VITROS* Immunodiagnostic Products Troponin I Calibrators are substantially equivalent to the DADE Dimension™ RxL Cardiac Troponin-I (TROP) Method.

1.1.5. Device Description

The *Vitros* Troponin I assay is performed using the *Vitros* Troponin I Reagent Pack and *Vitros* Immunodiagnostic Products Troponin I Calibrators on the *Vitros* ECi Immunodiagnostic System with Intellicheck ™ . An immunometric technique is used. Cardiac Troponin I present in the sample reacts simultaneously with a biotinylated antibody (mouse monoclonal anti-cTnI) and a horseradish peroxidase (HRP)-labeled antibody conjugate (affinity purified goat polyclonal anti-cTnI). The antigen-antibody complex is captured by streptavidin on the wells. Unbound materials are removed by washing. A reagent containing luminogenic substrates (a luminol derivative and a peracid salt) and an electron transfer agent (a substituted acetanilide) is added to the wells. The HRP in the bound conjugate catalyzes the oxidation of the luminol derivative, producing light. The electron transfer agent increases the level and duration of the light produced. The light signals are read by the *Vitros* ECi System. The amount of HRP conjugate bound is directly proportional to the concentration of cTnI present in the sample.

1.1.6. Device Intended Use

The *VITROS* Troponin I assay is intended for the *in vitro* quantitative measurement of Troponin I (cTnI) in human heparin plasma to aid in the diagnosis of myocardial infarction.

1.1.7. Comparison to Predicate Device

The *VITROS* Immunodiagnostic Products Troponin I Reagent Pack and *VITROS* Immunodiagnostic Products Troponin I Calibrators are substantially equivalent to the DADE Dimension RxL Cardiac Troponin-I (TROP) Method which was cleared by the FDA (K973650) for IVD use.

A comparison of the correlation data previously cleared (K992366) for *Vitros* Troponin I and modifications which are the subject of this Special 510 (k) are displayed in the table below.

This relationship was determined from a panel of patient samples from a variety of clinical categories.

	Vitros Troponin I K992366	*Vitros* Troponin I Modification
Number of Samples	122	198
Correlation Coefficient	0.983	0.949
Regression Equation	*Vitros* = 1.04 x Dade –0.151 ng/ml	*Vitros* = 0.728 x Dade –0.093 ng/ml
Range of Samples (*Vitros* Troponin I Values)	0.021 – 99.1 ng/ml	0.053 – 66.9 ng/ml

The upper reference limit for normals (URL) was set at 0.08 ng/mL based on a panel of 798 fresh heparin plasma samples from normal blood donors between the ages of 18-89 (61.3% male donors and 38.7% female donors collected across six sites). The observed values for the upper 97.5 percentile and the upper 99.0 percentile were 0.04 ng/mL (90% confidence interval 0.03 – 0.05 ng/mL) and 0.06 ng/mL (90% confidence interval 0.05 – 0.08 ng/mL), respectively. The URL represents the upper 90% confidence interval of the 99.0 percentile.

Data from a total of 458 chest pain patients, 78 of which were diagnosed with AMI were analyzed by Receiver Operator Characteristic (ROC) curve analysis to determine the best diagnostic cut-off for AMI using heparin plasma. The AMI cut-off was set at 0.4 ng/ml, representing a balance between sensitivity (85%) and specificity (91%).

A comparison of these limits from the previously cleared 510 (k) – K992366 for *Vitros* Troponin I and the modifications which are the subject of this Special 510 (k) are displayed in the table below.

Upper Reference Limit of Normals (Non AMI) in ng/ml	***Vitros* Troponin I K992366**	***Vitros* Troponin I Modification**
Serum	0.1	NA
Plasma	0.08	0.08
Higher Decision Limit (AMI cut-off) in ng/ml		
Serum	1.0	NA
Plasma	0.8	0.4

1.1.8 Conclusions

The intended use as cleared in K992366 is being limited from serum, EDTA and heparin plasma to heparin plasma only. The proposed changes described in this submission provide performance characteristics in line with this specimen type. These revisions provide data that continue to support the safe and effective use of the *Vitros* Troponin I Reagent Pack and Calibrators for use in quantitatively measuring Troponin I concentration in heparin plasma.Expected Values and Reporting Units.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Ann M. Quinn, RAC
Manager, Regulatory Affairs
Ortho Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101

APR 12 2002

Re: k020662
Trade/Device Name: *VITROS* Immunodiagnostic Products Troponin I Reagent Pack and *VITROS* Immunodiagnostic Products Troponin I Calibrators
Regulation Number: 21 CFR § 862.1215
Regulation Name: Creatine Phosphokinase/Creatine Kinase or Isoenzymes Test System
Regulatory Class: II Product Code: MMI
Regulation Number: 21 CFR § 862.1150
Regulation Name: Calibrator
Regulatory Class: II Product Code: JIT
Dated: February 28, 2002
Received: March 1, 2002

Dear Ms. Quinn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1.2 Statement of Intended Use

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510(k) Number (if known): K020662

Device Name: *VITROS* Immunodiagnostic Products Troponin I Reagent Pack

VITROS Immunodiagnostic Products Troponin I Calibrators

Indications for Use:

For the *in vitro* quantitative measurement of Troponin I (cTnI) in human heparin plasma to aid in the diagnosis of myocardial infarction.

For use in the calibration of the *Vitros* Immunodiagnostic System for the quantitative measurement of cardiac Troponin I (cTnI) in human heparin plasma.

Joan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020662

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)